UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,953	07/31/2003	Bozidar Ferek-Petric	P8856.04	1782

27581 7590 02/19/2010

MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER	
RAJAN, KAI	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
02/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/631,953	FEREK-PETRIC ET AL.	
	Examiner	Art Unit	
	Kai Rajan	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 42-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3-6, 46 ,47 and 49-59* is/are allowed.

6)☒ Claim(s) *1,2,42-45 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the reply filed November 5, 2009.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2009 has been entered.

Response to Arguments

Applicant's arguments have been fully considered. Arguments regarding claims 1 and 2 are not persuasive. In particular, Applicant contends that Steil et al. ("Steil") fail to disclose an IMD having means for monitoring administration of a drug. The Examiner disagrees. Steil disclose an insulin delivery system predominantly internal to the body that delivers insulin and has sensors for monitoring the body in response to delivered insulin. Since the user is monitored during and after the infusion of insulin, the administration of the drug is monitored. As such, the applied prior art is sufficient to reject claim 1 as currently presented.

Arguments regarding claims 3 – 6 were found persuasive, and the previous rejection has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 42, 44, 45, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Plicchi et al. U.S. Patent No. 5,609,612.

1. An interactive remote drug dose and physiologic response monitoring system in a patient under a prescriptive regimen to take a drug comprising:

a drug delivery device (Column 3 lines 43 – 67 drug delivery devices and infusion pumps in telemetry communication with a pacemaker); and

an implantable medical device (IMD) (Column 6 lines 26 – 39 implanted device including pacemaker) in wireless communication with the drug delivery device, the IMD having means for monitoring the administration of a drug by the drug delivery device in compliance with a prescriptive regimen (Column 3 lines 43 – 67, column 5 lines 21 – 60 pacemaker senses ECG signals of the patient while controlling a continuous drug dosage based on the needs of the patient),

wherein the IMD monitors the patient's physiological signs subsequent to the administration of the drug (Column 3 lines 43 – 67, column 5 lines 21 – 60 pacemaker senses ECG signals of the patient while controlling a continuous drug dosage based on the needs of the patient. Since the monitoring and dosing are continuous, the patient is monitored after portions of the dosing have been performed).

2. The system of claim 1, wherein the delivery device is chosen from one of the following: a pill box, a transdermal patch, a IV, an inhaler, an oral medicament dispenser, a subcutaneous implant, a drug pump, or a transcutaneous application (Column 3 lines 43 – 67 drug delivery devices and infusion pumps).

42. The system of claim 1, wherein the IMD modifies a therapy delivered by the IMD in response to the monitoring of the administration of the drug by the drug delivery device (Column 3 lines 43 – 67, column 5 lines 21 – 60 pacemaker senses ECG signals of the patient while regulating drug dosages based on the needs of the patient).

44. The system of claim 1, wherein the means for monitoring determines at least one parameter selected from the group consisting of:

drug intake by the patient in compliance with the prescriptive regimen (Column 3 lines 43 – 67, column 5 lines 21 – 60 pacemaker senses ECG signals of the patient while regulating drug dosages based on the needs of the patient);

whether the drug delivery device has administered a drug to the patient;

a dosage of a drug administered by the drug delivery device; and

an impact of administration of the drug on the IMD.

45. The system of claim l, further comprising:

means for logging monitored parameters of the drug delivery device (Column 7 lines 35 – 60 RAM and ROM store program and acquired data that oversee the operating phases of the device).

48. The system of claim 1, wherein the IMD is one of a neurostimulator or a cardiac stimulator (Abstract discloses the implanted device as a pacemaker).

Claims 1, 2, and 42 – 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Steil et al. U.S. PGPub No. 2003/0130616.

1. An interactive remote drug dose and physiologic response monitoring system in a patient under a prescriptive regimen to take a drug comprising:

a drug delivery device (Paragraphs 0005, 0006, 0090, 0093 insulin delivery system); and

an implantable medical device (IMD) (Paragraphs 0007, 0096 sensor system predominantly internal to the body) in wireless communication with the drug delivery device, the IMD having means for monitoring the administration of a drug by the drug delivery device in compliance with a prescriptive regimen (Paragraphs 0005, 0006 sensor system monitors the condition of the user including glucose concentration in response to insulin provided by the

infusion pump. The administration of the drug by the delivery device is monitored since the sensor detects changes in blood glucose, and the PID system adjusts infusion pump activity accordingly),

wherein the IMD monitors the patient's physiological signs subsequent to the administration of the drug (Paragraphs 0005, 0006, 0008 sensor system monitors the condition of the user including glucose concentration in response to insulin provided by the infusion pump, and the system compares glucose concentration levels to desired concentration levels to control the infusion pump).

2. The system of claim 1, wherein the delivery device is chosen from one of the following: a pill box, a transdermal patch, a IV, an inhaler, an oral medicament dispenser, a subcutaneous implant, a drug pump, or a transcutaneous application (Paragraph 0006 infusion pump).

42. The system of claim 1, wherein the IMD modifies a therapy delivered by the IMD in response to the monitoring of the administration of the drug by the drug delivery device (Paragraphs 0005, 0006, 0008 – 0014 sensor system monitors the condition of the user including glucose concentration in response to insulin provided by the infusion pump. The PID system adjusts infusion pump activity according to the difference between measured glucose levels and preset thresholds).

43. The system of claim 1, wherein the IMD checks drug interaction in the patient subsequent to the administration of the drug (Paragraphs 0005, 0006, 0008 – 0014 sensor system monitors the condition of the user including glucose concentration in response to insulin provided by the infusion pump).

44. The system of claim 1, wherein the means for monitoring determines at least one parameter selected from the group consisting of:

drug intake by the patient in compliance with the prescriptive regimen (Paragraphs 0005, 0006, 0008 – 0014 sensor system monitors the condition of the user including glucose concentration in response to insulin provided by the infusion pump. The PID system adjusts infusion pump activity according to the difference between measured glucose levels and preset thresholds);

whether the drug delivery device has administered a drug to the patient;

a dosage of a drug administered by the drug delivery device; and

an impact of administration of the drug on the IMD.

45. The system of claim l, further comprising:

means for logging monitored parameters of the drug delivery device (Paragraph 0327 stores sensor values corresponding to delivered drugs from the infusion pump and sent to the PID control system).

Allowable Subject Matter

Claims 3 – 6, 46, 47, and 49 – 59 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

February 12, 2010